K011350

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

The following summary is provided pursuant to Section 513(I)(3)(A) of the Federal Food, Drug, and Cosmetic Act.

A. Applicant Information

- ***Submitter:*** Orthomerica Products, Inc. 505 31st Street, P.O. Box 2927, Newport Beach, CA 92659, FDA Establishment Registration Number 1058152

- ***Contact:*** David C. Kerr, Chief Executive Officer, Telephone: (949) 723-4500, Facsimile: (949) 723-4501; Shannon R. Schwenn, Vice President, Manufacturing, Telephone: (407) 290-6592, Facsimile: (407) 290-2419

- ***Summary Date:*** May 2, 2001

B. Device Name and Classification

- ***Proprietary Name:*** STARband

- ***Common or Usual Name:*** Cranial Orthosis

- ***Classification Name:*** Cranial Orthosis

- ***Predicate Device:*** OPI Band, Cranial Orthosis, K001167, classified under 21 CFR § 882.5970.

C. Device Description

The STARband is a cranial orthosis used to treat abnormal head shape (clinically referred to as positional or deformational plagiocephaly) in infants ages 3 to 18 months. The orthosis applies mild pressure to the protruding areas of deformity and leaves room for growth in those areas of the infant's head that were flattened during deformation. The STARband is available only if prescribed by a physician.

The orthosis is custom made for each patient from a mold of the infant's head prepared from laser scanner measurements taken by a treating clinician using a specially designed laser scanner (STARscanner™) and e-mailed to Orthomerica. Orthomerica uses those measurements to fabricate a positive mold using a cad/cam system and a 5-axis router machine. The positive mold is then used to create the orthosis. Each orthosis is comprised of a an outer shell of plastic, an inner shell of foam, a strap and buckle for securing the orthosis, and a bellows mechanism for safety. The treating clinician modifies the orthosis for a precise fit, and monitors its use to ensure that no severe adverse reactions occur.

D. Intended Use

The STARband is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic- and brachycephalic-shaped heads. Orthomerica also intends to promote the use of the STARscanner™ as improving the accuracy, speed and convenience of the fabrication process as well as producing a reduction in the mental trauma to the infant and parents usually present in the manual casting process.

E. Comparison to Predicate Device

The STARband and its predicate device are very similar with respect to production, labeling, instructions for use, materials, safety and effectiveness, and special controls. The most significant difference between the two products is that the positive mold from which the STARband is fabricated is created using a laser scanner, cad/cam system and a 5-axis router machine versus the manual casting method utilized to create the positive mold for the OPI Band.

The proposed indications for the STARband are identical to those claimed by the predicate device with the exception of the additional claim stated above.

F. Performance Data

As indicated earlier, the STARband and the OPI Band as a finished product are identical. The safety and effectiveness of the OPI Band was confirmed to be substantially equivalent to its predicate device through a discussion of medical studies undertaken to demonstrate the effectiveness of cranial orthoses, a biocompatability assessment, and a bench test comparison of the pressure exerted by the device on an infant's head, and potential slippage of the devices under intended conditions of use. Therefore, because the completed devices are identical, these tests were not performed again and the previously discussed medical studies were not submitted again as part of this 510(k) submission.

Orthomerica did perform bench testing to determine whether the use of the laser scanner, cad/cam system and 5-axis router machine created a more precise positive mold from which to fabricate the cranial orthosis. The bench tests compared the measurements of the positive molds prepared using the above stated method and the manual casting method currently used to create the positive mold used to fabricate the OPI Band to a control sample and the laser scanning data. The method described above used to create the positive mold for the fabrication of the STARband cranial orthosis was found to be significantly more precise that the manual casting method.

Orthomerica has designed various protective measures to make sure that the use of the STARscanner™, cad/cam system and 5-axis router machine to measure the

infant's head and create the positive mold using those measurements does not cause any harm to the infant. The STARscanner™ is a Class I laser device, the lowest level of laser devices. In addition, each STARscanner™ will be equipped with a safety interlock which will prevent the laser beams from being emitted for longer than five seconds. The safety interlock feature will be tested by the manufacturer prior to shipment of the STARscanner™, by Orthomerica's technicians when they install the device and can be periodically tested by the treating clinician.

The measurments obtained by use of the STARscanner™ are checked by the treating clinician for irregularities in the data prior to being e-mailed to Orthomerica. Orthomerica's technicians review the data upon receipt and discuss any irregularities they observe in the data with the treating clinician prior to fabricating the positive mold. Finally, Orthomerica's quality control department checks each STARband prior to shipment to make sure all fabrication and modification guidelines have been followed and that it otherwise complies with the with the submitted measurements and the order form. The final check on the accuracy of the measurements and the fabrication process occur when the final fitting is done by the treating clinician and adjustments are made.

G. Summary

The safety and effectiveness data submitted to FDA establishes that STARband is safe and effective for its intended use and is substantially equivalent to applicable predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Orthomerica Products, Inc.
c/o Mr. William H. von Oehsen, III
Powell, Goldstein, Frazer & Murphy LLP
1001 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Re: K011350
Trade/Device Name: STARband
Regulation Number: 882.5970
Regulatory Class: II
Product Code: MVA
Dated: May 2, 2001
Received: May 2, 2001

Dear Mr. von Oehsen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If Known): K011350

DEVICE NAME: STARband

INDICATIONS FOR USE:

Intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic- and brachycephalic-shaped heads.

D Mutchler MD for CMW

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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